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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,590	09/30/1998	JEFFREY SCHLOM	2026-4230US1	8846

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OFFICE OF TECHNOLOGY TRANSFER
NATIONAL INSTITUTES OF HEALTH
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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,590

Applicant(s)

SCHLOM ET AL.

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10-15, 25, 27, 32-34, 66-68 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 72 is/are allowed.
- 6) ☐ Claim(s) 10, 27, 32-34, 68, 70 and 71 is/are rejected.
- 7) ☐ Claim(s) 11-15, 25, 66 and 67 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 10-15 and 72 have been amended. Claims 10-15, 25, 27, 32-34, 66-68 and 70-72 are pending and under consideration.

Acknowledgment is made of applicants amendment to the specification, filed October 6, 2003 to gain benefit under 35 U.S.C. 120 to application 08/.635,344, filed April 19, 1996. It is noted that rule 1.78 states

Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. This reference must be submitted during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. This time period is not extendable.

The amendment of October 6, 2003 fails to conform to the requirements for extending the filing date because it was filed too late in the prosecution to conform to said rule. Further, the originally filed disclosure and sequence listing of the '344 application does not support the genus of ras peptides now claimed. The '344 disclosure provides a written description (page 8, line 20 to page 9, line 6, and page 18, line 21) of

SEQ ID NO:1	KLVVVGAGGVGKS
SEQ ID NO: 2	KLVVVGADGVGKS
SEQ ID NO: 3	KLVVVGADGV
SEQ ID NO:4	KLVVVGAVGVG
SEQ ID NO:5	KLVVVGAGCVG
SEQ ID NO:6	YKLVVVGAV

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SEQ ID NO:10 KLVVVGAGGVGKS (same as SEQ ID NO:1)

SEQ ID NO:11 YLVVVGADGV

It is noted that only SEQ ID NO:11 conforms to the instant claim 1, specifying that when Xaa2 is V, then Xaa1 is Y. The disclosure of a single species does not provide support for the instant claimed genus. For all of the above reasons, the instant claims will be given the effective priority date of April 17, 1997.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10, 27, 32-34, 68, 70 and 71 are rejected under 35 U.S.C. 102(a) as being anticipated by Juretic et al (Int J of Cancer, November 15, 1996, Vol. 68, pp. 471-478).

Juretic et al disclose the peptide VGAVGVGKS which meets the limitations of claim 10 requiring a nine-mer from the motif set forth in claim 10. Juretic et al teach the generation of peptide specific CTL by stimulating PBMC with PBMC and tetanus toxoid, which fulfills the specific embodiment of claims requiring tetanus toxoid CD4 epitope. Juretic et al disclose that the peptides and tetanus toxoid were used in a mixture comprising recombinant Il2 and recombinant Il-4 which fulfills the limitations requiring the biological response modifier of Il-2 and a pharmaceutical composition comprising an antigen presenting cell because the PBMC would be induced to mature dendritic cells from monocytes in the presence of Il-2 and Il-4 and because the complete medium comprised human serum (page 471, second column, first full paragraph) which is pharmaceutically acceptable..

Claims 10, 27, 32, 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Gedde-Dahl et al (European Journal of Immunology, 1993, 23(3):754-760).

Gedde-Dahl et al disclose the peptide GAAGVGKSALAL (page 756, Figure 2) which meets the specific limitation of eliciting a mutant ras-peptide specific human CD+8 CTL immune response because human PBMC were used as APC. Gedde et al also fulfill the specific embodiments of claims requiring a pharmaceutical composition because autologous serum was

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used (page 755, first column, section 2.4) which is commensurate with a pharmaceutical composition for the donor of the serum.

Claim 72 is allowed.

Claims 11-15, 25, 66 and 67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicant's amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

11/12/2006


KARENA. CANELLA PH.D
PRIMARY EXAMINER